Harper Grace Hospitals
Harper Hospital Division
Nuclear Medicine

(62)

April 12, 1990

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attention: Docketing and Service Branch

Re: Basic Quality Assurance Program - Proposed Rule

Dear Secretary:

The following contains several issues of concern over the proposed amendments to 10 CFR Part 35. Following thorough and extensive review, we have determined that the proposed amendments are very vaguely worded and major clarifications are necessary.

Outlined below are a list of specific areas that are unclear and need further clarification or deletion:

PROPOSED 35.2

Clinical Procedures Manual - This definition should be removed from the rule. Inclusion of this item into the regulatory process infringes on the physician's right to practice medicine as he sees fit. Each clinical procedure should list "precautions," who and what determines these precautions.

Diagnostic Event - The addition of a new term is unnecessary, since the term "misadministration" is already understood and accepted. In your own words, "...misadministration be reserved for the most serious events..."; therefore, these other "events" are only a perceived problem.

PROPOSED 35.33

(a)(1) - "Any medical use not authorized in the license." Further clarification is needed for institutions with a Specific License of Broad Scope.

(b)(1) - "...and clinical procedure manual..." The inclusion of this is not necessary. It would be inconceivable that this manual be expected to cover every unique patient case, as this would result in the manual being in a constant state of revision. How will this requirement be regulated?

NRC

3990 John R., Detroit, Michigan 48201

DS10

- ...radiopharmaceutical or radiation to the wrong organ or site." Due to the patient's medical condition (e.g., shunts, organ pathology), a radiopharmaceutical could be administered to the wrong site. The word "radiopharmaceutical" should be omitted.

- "...via the wrong or unintended route..." This would require every subcutaneously injected intravenous dose to be reported. In large oncology and inner city institutions, IV access is often difficult, at best. The word "unintended" should be deleted.

(d) - "...what improvements are needed to prevent recurrence; actions taken to prevent recurrence..." This is redundant; one of these requirements should be removed.

- "...has the potential to cause serious harm to the patient..." Clarification is needed on who defines "serious harm," and how this will be regulated.

(e)(2) - "...written diagnostic clinical procedure..., for three years after its last use." The feasibility of this requirement is very questionable. It should be omitted.

PROPOSED 35.35

(a)(2) - This is redundant; please revise.

- Footnote - "...an oral instruction may be acceptable..." This is already regulated by state licensing bodies. It should be deleted.

(a)(3) - This is redundant; please revise.

The above comments are submitted in the hope of establishing a regulation that is beneficial to all concerned.

Sincerely,

Patricia J. Woodcroft

Patricia J. Woodcroft, CNMT
Supervisor, Nuclear Medicine

PJW:CIS

NRC